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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/517,981	03/03/2000	Julie A. Bearcroft	P01952US0	5566

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EXAMINER	
PELLEGRINO, BRIAN E	
ART UNIT	**PAPER NUMBER**
3738	

DATE MAILED: 08/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/517,981	BEARCROFT ET AL	
	Examiner	Art Unit	
	Brian E Pellegrino	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 May 2004* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16,20-22,26,64,65,67-77,79 and 80* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16,20-22,26,64,65 and 67-77,79,80* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15)☐ Notice of References Cited (PTO-892)
16)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17)☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18)☐ Interview Summary (PTO-413) Paper No(s). _____ .
19)☐ Notice of Informal Patent Application (PTO-152)
20)☐ Other:

DETAILED ACTION

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: the limitation that "*each of* the interstitial spaces of one particle will accept *only one* extremity of an adjacent particle" is not found in the written disclosure.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-4,9-11,14-16,20-22,26,64,65,69,70,73-77,79,80 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ahlers (5178201) in view of Black et al. (5676700). Ahlers discloses (Fig. 2) a shaped particle and additionally shows the particle with a plurality of the shaped particles to form an array. The shaped particle has a center portion **6** and at least six extremities **7** projecting from the center portion. The rounded extremities inherently have a circular transverse cross-section. Ahlers also discloses the particles have bilateral symmetry and the projections are the same shape and size, col. 2, lines 63-65. Ahlers additionally discloses the particles are used to permit bone ingrowth, col. 2, lines 46-48, col. 3, lines 8,9. Ahlers also discloses the particles can be made of polypropylene (a polymer), col. 3, lines 16-18. The diameter of the particle can be about 6mm, col. 4, lines 16-18. However, Ahlers fails to disclose the

extremities as being tapered. Ahlers also does not disclose bioactive glass for the particles. Black teaches (Fig. 1) a shaped particle **10** having a center portion **C** and tapered extremities **12** projecting from the center portion. Black also teaches the particle is made of materials such as ceramic or bioactive glass, col. 4, lines 14-18. Black additionally teaches the shaped particle is used for repair of bone, i.e. in diseased bone, voids in bone, col. 1, lines 30-60. Fig. 4 illustrates an array of a plurality of shaped particles. Black also teaches that the extremities are tapered to enhance meshing and interlocking of the extremities in a tight relationship, col. 3, lines 34-38. It would have been obvious to one of ordinary skill in the art to use tapered extremities as taught by Black et al. with the particles of Ahlers such that it enables the particles to be interlocked tightly and also provide mechanical properties at the area of use.

Claims 5, 6,12,13,67,68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ahlers '201 in view of Black et al. '700 as applied to claim 4 and 26 above, and further in view of Chen et al. (6180606). Ahlers in view of Black et al. is explained supra. However, Ahlers as modified by Black et al. do not disclose the claimed materials for the particles or composite materials. Chen et al. teach that compositions used in periodontal repair are formed of calcium compounds, col. 2, lines 13-25. Polymers such as polylactic acid can be used for the matrix and composites can also be formed of polymer/ceramic or glass combinations, col. 3, lines 40, 41, 47-50, 60-65. It would have been obvious to one of ordinary skill in the art at the time of the invention to substitute different ceramics and use calcium phosphate or combinations of materials such as polymer composites as taught by Chen for the particles of Ahlers as

modified by Black et al. in order to enhance the osteogenic potential of the composition being used.

Claims 7,8,71,72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ahlers '201 in view of Black et al. '700 as applied to claim 6 and 70 respectively above, and further in view of Barralet (Biomaterials, 1993). Ahlers in view of Black is explained supra. However, Ahlers as modified by Black do not disclose the ceramic as gypsum or the array to have a porosity between 40-80%. Barralet teaches that calcium sulfate or gypsum having a porosity of 60%, see Abstract. It would have been obvious to one of ordinary skill in the art to use calcium sulfate as taught by Barralet for the shaped particles of Black in order to provide a well accepted bone filler with a good porosity for bone ingrowth.

Regarding claim 65, Ahlers in view of Black et al. do not disclose resorbable materials for the particles. It would have been an obvious matter of design choice to have a resorbable material for the shaped particle, since applicant has not disclosed that this material for the particle provides any advantage, or is used for any particular purpose, or solves any stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with either the ceramic or bioactive glass as taught by Ahlers in view of Black or the resorbable material of claim 65 because both materials are biocompatible and remain in the body of a sufficient time to permit bone ingrowth and provide the ability to fill the bone void.

Response to Amendment

The declaration under 37 CFR 1.132 filed 5/11/04 is insufficient to overcome the rejection of claims 1-4,9-11,14-16,20-22,26,64,65,69,70,73-77,79,80 based upon Ahlers in view of Black as set forth in the last Office action because: the references are both in the same field of endeavor since they both deal with treatment of a bone deficiency, such as bone repair or replacement and are clearly combinable. Black clearly provides a motivation to combine with the Ahlers reference, in that Black teaches tapering of the extremities enhances interlocking of the particles. Ahlers also discloses the particles do provide a scaffold for bone ingrowth, which is clearly involved in repair of bone. Regarding the materials comments, note that claims 4,10,11 are disclosed by Ahlers and thus the arguments are moot.

Response to Arguments

Applicant's arguments filed 5/11/04 have been fully considered but they are not persuasive. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Black '700 clearly provides a motivation to use tapered extremities in a particle because it

enhances interlocking, col. 3, lines 35-38. This would clearly improve the use of particles on the Ahlers' prosthesis since the particles would be interlocked together in addition to being bonded to the surface. In response to applicant's argument that the shaped particle cannot be used to fill a bony defect, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Applicant also contends that the Ahlers' particles are incapable of providing a scaffold for bone ingrowth is unpersuasive because Ahlers clearly discloses that the particles do provide a matrix or scaffold for bone ingrowth, col. 2, lines 46-48, col. 3, lines 8,9. Regarding the comments about materials, please note that claim 4 is a Markush type claim and recites the particle can be a polymer, clearly taught by Ahlers (col. 3, lines 16-18) and since the claims that depend from claim 4 do not even further define the Markush recitation of a polymer (disclosed by Ahlers) all claims depending from claim 4 could even be ignored and not required to be even considered.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Pellegrino whose telephone number is (703) 306-5899. The examiner can normally be reached on Monday-Thursday from 8:30am to 6pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached at (703) 308-2111. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

TC 3700, AU 3738

Brian E. Pellegrino

Brian E Pellegrino

BRUCE SNOW
PRIMARY EXAMINER